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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,566	03/13/2002	Hiroshi Kayahara	216120US0PCT	8672
22850	7590	08/16/2004		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,566

Applicant(s)

KAYAHARA ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7,8,11,13 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,7,8,11,13 and 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/02.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Acknowledgment is made of the receipt and entry of the amendment filed on May 25, 2004. Acknowledgment is made of Applicant's cancellation of Claim 3, and newly added Claim 21.

#### ***Allowable Subject Matter***

At the outset, Applicants thanks the Office for indicating that Claim 3 is allowable in the previous Office action. However, the indication for the allowability of subject matter in the present application is herein vacated because Applicant did not insert all of the limitations of Claim 3, as originally presented, into base Claim 1 as advised and for the reasons set forth below in the rejection made under 35 U.S.C. 112, second paragraph, and set forth immediately below.

#### ***Election/Restrictions***

As set forth immediately above and as set forth below in the rejection made under 35 U.S.C. 102(b), Claim 1 as amended does not make a novel contribution over the prior art. Thus, the request for rejoining Claims 4,5,7,8,11,13 and 17-21 along with Claims 1 and 2 cannot be satisfied.

The finality of the restriction requirement set forth in the previous Office action remains FINAL.

**Claims 1 and 2 are under examination.**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 as amended remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 1 are rendered vague and indefinite by the phrase “a grain of a rice plant which is in a germinated form” because it is unclear as to the subject matter Applicant intends to direct the invention. For example, it is uncertain whether the instantly claimed extract is obtained from a germinated rice grain or from a grain of rice obtained from a germinated rice plant. Moreover, if the extract is obtained from a germinated grain of rice, it is unclear whether the extract is obtained from a cotyledon or a seed leaf or a bud? The lack of clarity renders the claim very ambiguous.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Tokuyama (N, translation of foreign patent provided herein).

Applicant claims a prolylendopeptidase-inhibitive agent comprising an extract of a grain of a rice plant which is in a germinated form.

Tokuyama teaches an extract of germinating rice. It is noted that the reference does not teach that the composition can be used in the manner instantly claimed (*i.e.*, a prolylendopeptidase-inhibitive agent), however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

The reference anticipates the claimed subject matter.

### ***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokuyama (N) in view of Maruyuma et al. (AX), Dziuba et al. (U) and Miyoshi et al. (V). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claim 1 was set forth above. Applicant further claims the prolylendopeptidase-inhibitive agent according to Claim 1 further comprising a cereal grain as an active component, wherein the cereal grain is a grain or seed of at least one member selected from the group consisting of wheat, corn, soybean, milo, buckwheat, foxtail millet, barnyard grass, proso and sesame.

The teachings of Tokuyama are set forth above. Tokuyama teaches the claimed composition except for the instantly claimed ingredients. However, it would have been obvious to one of ordinary skill in the art to add a cereal grain to the composition taught by Tokuyama to provide the instantly claimed composition because at the time the invention was made Maruyuma teaches an extract of a maize endosperm and an extract of soybean comprising prolylendopeptidase inhibiting agents, and the use thereof for treatment of cerebral dysfunction; Dziuba teaches extracts of barley, rice, sorghum and oat comprising prolylendopeptidase-inhibitive agents, in Table 4 on page 36, and; Miyoshi teaches an extract of corn comprising a prolylendopeptidase-inhibitive agent having therapeutic activity for the treatment of amnesia, on page 430, lines 3-5. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the

ingredients taught by Maruyuma, Dziuba and Miyoshi to the composition taught by Tokuyama because each of the compositions taught by Maruyuma, Dziuba and Miyoshi comprise an inhibitor prolylendopeptidase which can be used in the treatment of cerebral dysfunction like the composition taught by Tokuyama. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**MICHELE FLOOD**  
**PATENT EXAMINER**

MCF  
August 5, 2004